



WHAT IS CLAIMED IS:

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- 1. A pharmaceutical composition comprising particulate valdecoxib in an amount of about 1 mg to about 100 mg per dose and one or more pharmaceutically acceptable excipients, wherein a single dose, upon oral administration to a fasting subject, provides a time course of blood serum concentration of valdecoxib having at least one of
 - (a) a time to reach a threshold concentration for therapeutic effect not greater than about 0.5 h after administration;
 - (b) a time to reach maximum concentration (T_{max}) not greater than about 5 h after administration; and
 - (c) a maximum concentration (C_{max}) not less than about 100 ng/ml.
- 2. The composition of Claim 1 wherein the threshold concentration for therapeutic effect is about 20 ng/ml.
- 3. The composition of Claim 2 wherein a single dose, upon oral administration to a fasting subject, provides a time course of blood serum concentration of valdecoxib having each of
 - (a) a time to reach a concentration of 20 ng/ml not greater than about 0.5 h after administration;
 - (b) a time to reach maximum concentration (T_{max}) not greater than about 3 h after administration; and
 - (c) a maximum concentration (C_{max}) not less than about 100 ng/ml.
- 4. The composition of Claim 1 wherein the valdecoxib is in an amount of about 5 mg to about 40 mg per dose.



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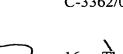
- 5. The composition of Claim 1 that is a tablet wherein the excipients comprise one or more diluents in an amount of about 5% to about 99%, one or more disintegrants in an amount of about 0.2% to about 30%, one or more binding agents in an amount of about 0.5% to about 25%, and one or more lubricants in an amount of about 0.1% to about 10%, by weight of the composition.
- 6. The composition of Claim 5 wherein the binding agent is pregelatinized starch.



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- The composition of Claim 1 that is a tablet wherein the excipients comprise lactose monohydrate, microcrystalline cellulose, croscarmellose sodium, 7. pregelatinized starch and magnesium stearate.
- The composition of Claim 1 further comprising one or more opioid or analgesic 8. drugs.
- The composition of Claim 1 wherein D_{90} of the valdecoxib particles is less than 9. about 75 µm.
- The composition of Claim 1 wherein the valdecoxib particles have a weight average particle size of about 1 to about 10 μm . 10.
- A process for preparing a composition of Claim 5 comprising a step of wet cald axib together with one or more diluents and a binding agent, a step of drying the resulting granules and a step of compressing the resulting dry 10 granulate to form a tablet.
 - The process of Claim 11 wherein, prior to the wet granulating step, valdecoxib is mixed under low shear with one or more diluents and a binding agent to form a premix for wet granulation; and wherein, between the drying step and the 12. compressing step, the granules are blended with a disintegrant and a lubricant to form a blend for tableting.
 - The process of Claim 12 wherein the binding agent is pregelatinized starch.
 - The process of Claim 13 wherein the diluents comprise lactose monohydrate and 13. microcrystalline cellulose, the disintegrant is croscarmellose sodium and the 14. 20 lubricant is magnesium stearate.
 - The process of Claim 11 wherein, prior to the wet granulating step, valdecoxib is mixed under high shear with a primary diluent, a first portion of a secondary diluent, a binding agent and a first portion of a disintegrant, to form a premix for 15. wet granulation, and wherein, between the drying step and the compressing step, 25 the granules are blended with a second portion of the secondary diluent, a second portion of the disintegrant, and a lubricant, to form a blend for tableting.

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- 16. The process of Claim 15 wherein the binding agent is pregelatinized starch.
- 17. The process of Claim 16 wherein the diluents comprise lactose monohydrate and microcrystalline cellulose, the disintegrant is croscarmellose sodium and the lubricant is magnerium stearate.
- 5 18. A method of treating a medical condition or disorder in a subject where treatment with a cyclooxygenase-2 inhibitor is indicated, comprising orally administering to the subject a composition of Claim 1 once or twice a day.